UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

Sarah Lampron and
Walter Lampron

v.

Civil No. 20-cv-317-JD
Opinion No. 2020 DNH 098

Ethicon, Inc. and
Johnson and Johnson

O R D E R

Sarah and Walter Lampron bring a product liability action, arising from injuries Sarah Lampron alleges that she incurred from surgically implanted mesh made by Ethicon, Inc. The case was recently transferred to this court from multidistrict litigation, In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, (S.D.W. Va. filed on March 4, 2015). The Lamprons move to preclude the defendants' expert witness, Dr. Joseph Carbone, from providing certain opinions.[1] The defendants object to the motion.

Standard of Review

The admissibility of expert opinion evidence is governed by Federal Rule of Evidence 702. Rule 702 provides that "[a] witness who is qualified as an expert by knowledge, skill,

[1] The Lamprons appear to have filed the motion twice. Docs. Nos. 59 and 60. The defendants responded to document no. 60.

experience, training, or education may testify in the form of an opinion or otherwise if" four requirements are satisfied. Those requirements are:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to under the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods, and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The proponent of the expert's opinion bears the burden of showing that it is admissible. Milward v. Rust-Oleum Corp., 829 F.3d 469, 473 (1st Cir. 2016); United States v. Tetioukhine, 725 F.3d 1, 6 (1st Cir. 2013).

Discussion

The Lamprons challenge Dr. Carbone's opinions about the safety and efficacy of the defendants' mesh products, the design of the products, and the adequacy of the warnings in the instructions for use of the products. They contend that Dr. Carbone is not qualified to give those opinions and that the opinions are not reliable due to a lack of research to support them. In response, the defendants argue that Dr. Carbone's clinical experience supports his opinions, that he is qualified to give his opinions, and that his design opinions are based on reliable methodology.

Dr. Carbone produced two reports that address different products. One report addresses TVT, TVT-O, and TVT-Secur and the other addresses Prolift. The Lamprons represent that the two reports contain the same opinions.

A. Safety and Efficacy of Defendants' Mesh Products

The Lamprons seek to exclude Dr. Carbone's testimony about safety and efficacy rates based on his own experience with the defendants' products. More specifically, the Lamprons object to Dr. Carbone's statement that he had no complications in using Prolift. They contend that his opinion is not reliable because it is based on an undisclosed summary prepared by his office manager, because he did not do an investigation or a survey to determine how many Prolift complications had occurred, and because he did not consider Prolift separately from other prolapse product failures. Due to the lack of data to support the opinion, the Lamprons contend that they have no way to test the reliability of Dr. Carbone's opinion.

In response, the defendants contend that Dr. Carbone's opinion on safety and efficacy is reliable because it is based on his forty or fifty mesh removal procedures and on his review of relevant medical literature. They explain that Dr. Carbone had his office manager code his removal procedures, based on the International Classification of Diseases coding, to show whether

the removal was required due to erosion of the product. Based on his office manager's coding, Dr. Carbone decided that his complication rate was slightly less that the rates reported in medical literature. The defendants contend that Dr. Carbone's method was reliable and that he was not required to conduct any other survey or investigation.

The defendants also state that the Lamprons' attorney elicited the complication rate opinion from Dr. Carbone during his deposition and that Dr. Carbone did not include an opinion in his expert reports about his own complication rates with the defendants' products.[2] An expert opinion must be disclosed in an expert report. Fed. R. Civ. P. 26(a)(2)(B)(i). A failure to comply with that rule may be grounds to exclude the opinion, even when the opinion was offered during a deposition. Fed. R. Civ. P. 37(c)(1); see also Arrieta v. Hosp. Del Maestro, 2018 WL 3425295, at *2 (D.P.R. July 13, 2018) (citing cases).

In addition to the disclosure error, the defendants have not persuasively shown that Dr. Carbone's opinion about his own complication rate is based on a reliable methodology. The

[2] It is unclear what significance the defendants place on that circumstance. The defendants argue, however, that other disclosed opinions are sufficient to meet their disclosure obligations. The opinions in the reports cited by the defendants do not appear to include the complication rate opinion that is based on Dr. Carbone's office manager's coding system.

defendants provide no information about International Classification of Diseases coding or Dr. Carbone's office manager's qualification and training to perform the coding that is the basis for his opinion. Although those deficiencies might be addressed through cross examination, the combination of the lack of disclosure and the questionable methodology precludes Dr. Carbone's complication rate opinion. Therefore, Dr. Carbone's opinion about the safety and efficacy of the defendants' products, based on his own experience, is excluded.

B. Opinions on Safety and Efficacy of Design

The Lamprons challenge Dr. Carbone's opinions that the defendants' products were reasonably safe for their intended use, that their benefits outweigh the risks, and that they are safer and more effective than non-mesh alternative products. They contend that he lacks the knowledge and experience necessary to be a design expert for purposes of those opinions. The defendants contend that Dr. Carbone is qualified to provide opinions about safety and efficacy of the design of the defendants' products based on his own clinical experience using and removing their products.

The first challenged opinion is part of a section titled "PROFESSIONAL ENDORSEMENTS." It is not clear that Dr. Carbone is providing his own opinions in that section. Instead, he

appears to be summarizing the opinions provided by medical organizations and the FDA.

The second challenged opinion is a discussion about the invention and use of Prolift products. Dr. Carbone's discussion concludes with the following:

> In summary, Prolift has been demonstrated to be safe and effective. Longer term studies continue to show its efficacy and safety. While there have been claims of the mesh roping and curling by experts of the Plaintiff, when placed according to the IFU and the arms detensioned the mesh will lie flat. Claims have been made regarding alternative meshes being better however, the overall data show that the Type 1 macroporous Prolene mesh in Gynemesh PS is suitable for use in pelvic organ prolapse and the mesh has been studied more and for longer follow up than others. The theory that an even larger pore and lighter weight mesh would be better has not shown to be true. One such mesh, Vypro, was studied by the TVM Group and found to not be tolerable. Other meshes do not have a higher efficacy profile nor have the data shown them to be safer overall. There is still a risk of mesh exposure with the use of any mesh. As an example, the rates of exposure with Prolift+M which uses Ultrapro mesh are not lower than the rates in Prolift which uses Gynemesh PS. The data has demonstrated that both are suitable options to treat prolapse. Dyspareunia is always a risk with or without mesh and, as discussed earlier, the risk of dyspareunia, pelvic pain and sexual dysfunction with Prolift is no different than native tissue repairs. There have also been claims that the mesh degrades, is cytotoxic, leads to an adverse significant inflammatory response, and that it causes sarcoma formation or cancer. However, the clinical data is inconsistent with this theory as there are long-term studies of efficacy and safety. Additionally, the macroporous Prolene material has been studied in the body for up to 17 years showing its long-term biocompatibility. The data do not show a malignant risk.

Doc. 60-4, at *24-*25.

It is not entirely clear what specific opinions the Lamprons seek to exclude as design opinions.[3] To the extent Dr. Carbone provides opinions about the safety and efficacy of the defendants' products based on his personal complication rate, that opinion is excluded for the reasons stated above. To the extent the challenged opinions are Dr. Carbone's interpretations of the medical literature, which seems to be the case, those opinions may be challenged on cross examination based on the infirmities raised by the Lamprons in their motion.

C. Opinions on Adequacy of Warnings

The Lamprons challenge Dr. Carbone's opinions that the warnings provided in the instructions for use of the defendants' products are adequate. They contend that he lacks the necessary expertise in warnings and has admitted that he is not an expert on warnings, that he does not know the industry or regulatory standards for warnings, does not know what standards Ethicon used in composing its warnings, and does not rely on instructions for use. In response, the defendants acknowledge that Dr. Carbone's opinions about the adequacy of the

[3] The defendants state that Dr. Carbone does not provide any opinions on design of their products and cites a decision from the MDL that a challenge to Dr. Carbone's design opinions was moot.

instructions for use are limited to whether the specific risks of implanting mesh were included.

In the first challenged opinion, Dr. Carbone states:

> Instructions for use (IFU) accompany all medical devices like the TVT. An IFU is not intended to serve as a comprehensive guide for a surgeon. Instead, it provides information about the device, the procedure, the indications, and warnings and precautions that the surgeon can use in conjunction with his or her training and experience. A reasonably prudent surgeon will be trained in pelvic floor surgery, with or without mesh, before he or she attempts to implant a TVT. An IFU only supplements that training and experience.
>
> The TVT IFU adequately warns of all risks and potential complications associated with the TVT. These risks are well known to the medical community. Even the FDA has acknowledged that that risks known to be common to pelvic floor surgery (even without mesh) include pain, infection, urinary problems, recurrent incontinence, pain during sexual intercourse (dyspareunia), bleeding, organ perforation, neuoro-muscular problems and vaginal scarring.1
>
> The TVT IFU fairly and completely informs reasonably prudent surgeons about the TVT, including the procedure and the associated risks and potential complications.
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> 1 FDA, Considerations About Surgical Mesh for SUI, April 2, 2013. U.S. Food and Drug Administration http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345219.htm downloaded Feb 10, 2016.

Doc. 60-3, at *21. Given the acknowledged limitations, Dr. Carbone's opinion is limited to the highlighted paragraph and the remainder is excluded.

In the second challenged opinion, Dr. Carbone states:

> Instructions for use (IFU) accompany all medical devices like the Prolift. An IFU is not intended to

> serve as a comprehensive guide for a surgeon. Instead, it provides information about the device, the procedure, the indications, and warnings and precautions that the surgeon can use in conjunction with his or her training and experience. A reasonably prudent surgeon will be trained in pelvic floor surgery, with or without mesh, before he or she attempts to implant a Prolift. An IFU only supplements that training and experience.
>
> The Prolift IFU adequately warned of all risks and potential complications associated with the Prolift. These risks were well known to the medical community.

Doc. 60-4, at *26. That statement does not include any opinion about whether specific risks of implanting mesh were included in the instructions for use. Therefore, that opinion is beyond the allowable scope for Dr. Carbone and is excluded.

Conclusion

For the foregoing reasons, the plaintiffs' motions to preclude certain opinions by Dr. Carbone (documents 59 and 60) are granted in part and denied in part as is provided above.

SO ORDERED.

Joseph A. DiClerico, Jr.
United States District Judge

June 8, 2020

cc: Counsel of record.